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GB 2199250 A GB 2157567 A US 4204540 A

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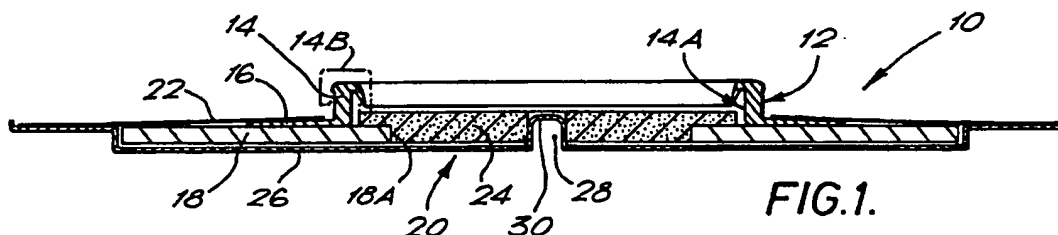
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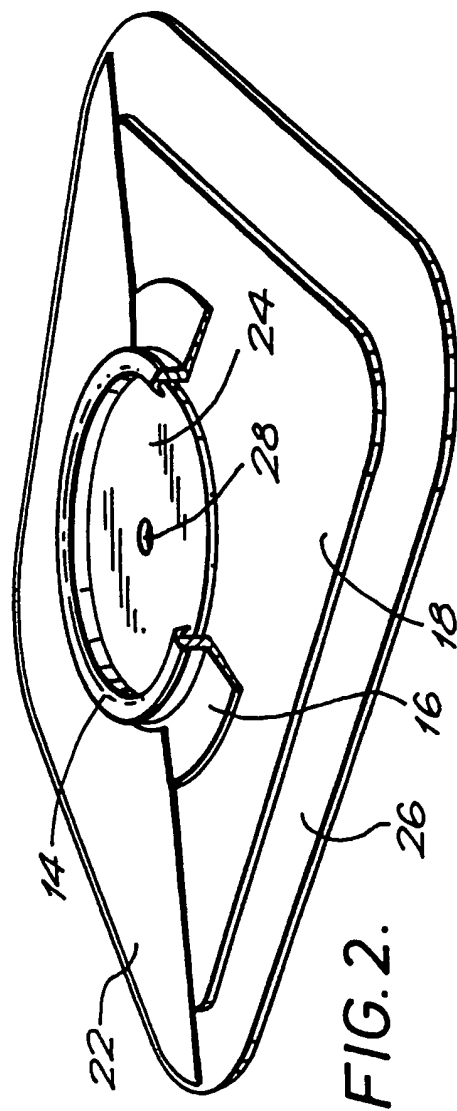
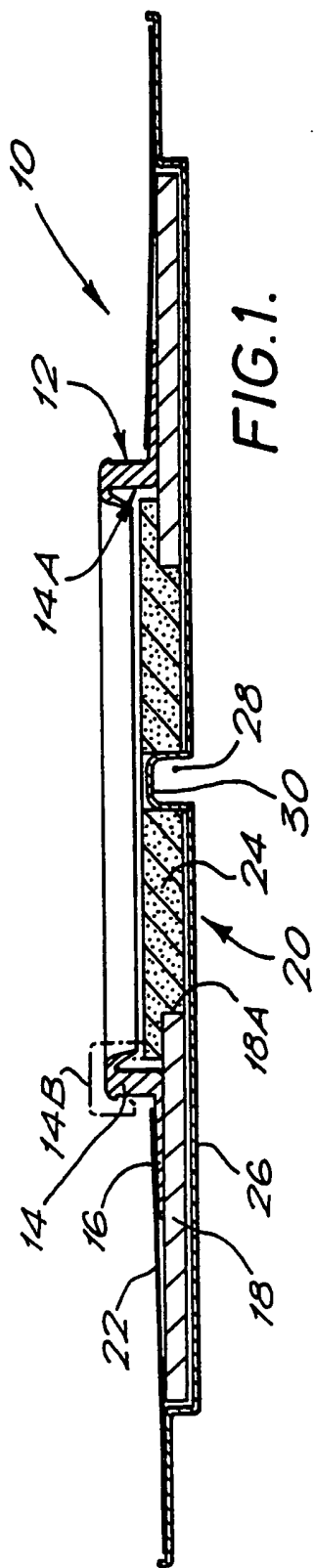
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(54) **Body-side ostomy member**

(57) The member comprises a ring 12 to which a bag, or coupling ring therefor, can be attached, the ring having an annular flange 16 extending radially outwardly of a rib 14 which surrounds the stomal orifice. The flange is mounted on a wafer 18 of medical grade adhesive having a central hole 20 of diameter at least 65% of the internal diameter of the ring. A mouldable mass 24 of non-hypoallergenic, non-memory putty-like adhesive, particularly based on hydrocolloid or hydrogel, is disposed radially inward of the rib and wafer and has a thickness of 1.25 - 3 times that of the wafer and a central hole therein of diameter no more than 1/10th of the internal diameter of the ring. A peelable cover layer 26 may be provided.



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BODY-SIDE OSTOMY MEMBER

This invention relates to a body-side ostomy member.

5 Ostomy appliances are well known. Our successful design is shown
in U.K. Patent No. 1 571 657 (Kingsdown). Such an appliance may be two-
piece or one-piece. A body-side member is normally attached to a medical
grade adhesive wafer or pad which, once a cover layer has been pulled off,
is stuck to the skin of the wearer of the appliance over the peristomal region.
Known adhesive wafers have a hole therein. The general practice of
ostomates using either one or two piece appliances has been to cut out the
10 adhesive centre to suite their stoma size, using one of the 32mm, 38mm,
45mm, 57mm, 70mm or 100mm body-side wafers, then fit the appliance and
often use a medical grade adhesive paste such as that sold by Bristol-Meyers
Squibb under the Trade Mark "Stomahesive" to fill around the edge of the
stoma and cut the shaped hole. Ostomates alternatively can if desired
15 purchase a range of 'pre-cut' wafers in which the adhesive area is pre-cut to
set diameters for each of the above-mentioned range of products.

 This is to some extent wasteful of material and involves the ostomate
in a troublesome series of actions. Many ostomates, especially those who are
old or infirm are not naturally dexterous at cutting accurately located and
20 accurately sized holes on a material which is not easy to work with. Such
ostomates desire a simpler and more efficient way of achieving a comfortable
fitting of a body-side coupling member.

 It is an aim of the invention to provide an improved body-side ostomy
member.

25 According to one aspect of the present invention, there is provided a
body-side ostomy member in which an encircling rib thereof surrounds and
confines a mouldable mass of non-hypoallergenic, substantially non-memory
putty-like adhesive which is such that it can be finger-spread so that it forms

a doughnut-like cushioning and protective mass surrounding the stoma.

According to another aspect of the present invention, there is provided a body-side ostomy member comprising a ring to which a bag-side coupling ring, or a bag, can be attached, said member comprising a preferably annular flange extending radially outwardly of a rib which surrounds the stomal orifice, the flange being mounted on a wafer of medical grade adhesive having a central preferably circular hole therein whose diameter is at least 65 % of the I.D. (internal diameter) of the ring, there being a mouldable mass of a non-hypoallergenic, substantially non-memory putty-like adhesive disposed radially inwardly of the wafer and having a thickness of at least 1.25 times that of the wafer and not more than three times that of the wafer, said mouldable mass having a central hole therein whose diameter is no greater than 1/10TH of the I.D. of the ring.

According to an advantageous embodiment of the invention, in the cases of a two-piece appliance, the rib may have a flexible deflectable seal strip extending inwardly from its radially inner wall surface.

The mouldable putty-like mass preferably has very little or no memory, preferably is hydrocolloid-based, or hydrogel-based, or alternatively an adhesive which may be plastic in nature during digital deformation but after being placed on the body, water absorption will render it elastic by cross linking and thus no longer motile. Furthermore, the mouldable putty-like mass and is of a structure and consistency such that it can be spread with single digit motion and thereby spread out so that the space between the stoma and the radially inner edge of wafer is filled with the mouldable mass which is pressed to snugly surround the stoma. In other words, the mouldable mass is pressed and packed by the wearer into the space between the stoma and the body-side ring to form a doughnut-like cushioning and protective mass which is a snug, tailored fit within that space. No extra paste or adhesive need be supplied, and a notable advantage of the invention specifically described is

that, instead of say 6 or more different sizes, the use of this mouldable mass enables virtually all ostomy patients to wear one of two sizes, 40mm and 60mm. The sizing convention relevant to the present applicants' ostomy appliances is that the appliance is sized according to the diameter of the stomal aperture.

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In a preferred embodiment of the invention, an annular ring of adhesive tape such as that known as "Micropore" (Trade Mark) and available from the 3M Company may be arranged to partly overlie the upper (i.e. outer when worn) surface of the flange and partly overlie the adjacent surface of the wafer. The wafer may be made of a hydrocolloid or polyurethane adhesive, and preferably is about 2mm thick, though a greater or lesser thickness may be used. Instead of the "Micropore" tape referred to, one may employ a thin annulus of polyurethane foam.

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This invention will be better understood from the following description given by way of example, of a body-side ostomy member according to a preferred embodiment of the invention. In the accompanying drawings,

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Figure 1 is a cross section on a plane intersecting the axis of revolution of a body-side ostomy member; and

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Figure 2 is a perspective view, partly cut away, of the member shown in Figure 1.

The illustrated body-side member is shown as one member of a two-piece ostomy appliance, but the principles of the invention, and a largely similar construction, could be used for a one-piece appliance. In the latter case, the bag would be attached directly to the body-side ring.

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Referring firstly to Figure 1, the body-side member 10 has a ring 12 having a circular rib 14 and a flange 16. The flange 16 is mounted on a wafer 18 of medical grade adhesive having a central circular hole 20 therein. This hole 20, assuming a 40mm size appliance, may be from about 26 to 37mm in diameter, preferably approximately about 29mm. The thickness of

the wafer may be from about 1.75 to about 2.5mm. An annular 22 of "Micropore" adhesive tape or polyurethane foam overlies the flange 16 and the portion of the wafer 18 outwardly of the flange. Located within the rib 14 and substantially filling the space bounded by the wall 18A of the wafer 18, is a mouldable mass 24 of a substantially non-memory putty-like adhesive having a fairly firm consistency. Its consistency is chosen so that it can be manipulated and pressed into position by the action of one or more fingers of the ostomate. The mass is non-hypoallergenic and may be hydrocolloid or hydrogel-based. Its thickness, in the product as delivered, is in the range about 3 to 4.2 preferably about 3.8mm. It will be understood that when pressed into position around the stoma its thickness may differ from this range, and will vary from place to place due to varying pressures applied by the finger when packing it snugly around the stoma. In this process, some radial expansion and reduction in thickness of the mass is likely to occur, the expansion being limited by the inner wall 14A of the rib 14. A cover layer 26, which is peeled away when the appliance is to be stuck on the skin of the ostomate, extends over the whole of the lower (skin adhering) surface of the wafer 18 and the mouldable mass 24. A flexible and deflectable peripheral sealing strip 14B is integral with the rib 14, and serves to provide a seal between the ring 12 and a counterpart bag-side ostomy coupling member. The strip 14B forms no part of the novelty of this invention; for further information the reader is referred to British Patent No. 1 568 860.

The mouldable mass 24 preferably has a central hole 28 therein, and the cover layer is shaped as seen in Fig. 1 with a cup shaped protuberance 30 which extends into the hole 28. One purpose of this arrangement is to assist in locating the cover layer accurately on the body-side ring during manufacturing assembly. The cover layer may be made of a plastic material, for example polyethylene terephthalate.

In this specification the terms "ring", "circular" and "annular" have

5 been used in relation to the shape of the ostomy member 10 and ring 12. It will be appreciated by those skilled in art that a ring of any closed loop form, e.g. oval, could be employed instead of a circular ring, without sacrificing the advantages of the invention. This specification and claims are accordingly to be construed as including ostomy body members and ostomy appliances which have a ring of any closed loop shape.

10 The wafer 18 is a medical grade pressure sensitive adhesive, e.g. a microporous acrylic type such as that taught by Copeland in United States Patent 3,121,021 or a hydrocolloid containing microporous adhesive as taught by Cilento *et al* in European Patent Application No. 63,898 published on November 3, 1982. The backing or cover layer 26 can be a breathable non-woven material such as one of the commercially available spun-bonded polyester products.

15 Alternatively, the wafer 18 may consist of a non-porous pressure sensitive adhesive layer with a polymeric backing film 26. A particularly suitable adhesive wafer of this type is taught by Chen in United States Patent 3,339,546 and consists of an elastomeric substance such as polyisobutylene and one or more water soluble or swellable hydrocolloids such as the mixture of pectin, gelatin, and sodium carboxymethylcellulose having an impervious polymeric film secured to one surface. Other suitable adhesive wafers of this type are taught by Chen *et al* in United States Patent 4,192,785 and by Pawelchak *et al* in United States Patent 4,393,080.

CLAIMS

1. A body-side ostomy member comprises a ring to which a bag-side coupling ring, or a bag, can be attached, said member comprising a preferably annular flange extending radially outwardly of a rib which surrounds the stomal orifice, the flange being mounted on a wafer of medical grade adhesive having a central preferably circular hole therein whose diameter is at least 65 % of the I.D. (internal diameter) of the ring, there being a mouldable mass of a non-hypoallergenic, substantially non-memory putty-like adhesive disposed radially inwardly of the wafer and having a thickness of at least 1.25 times that of the wafer and not more than three times that of the wafer, said mouldable mass having a central hole therein whose diameter is no greater than 1/10TH of the I.D. of the ring.
2. A member according to claim 1 in which, in the cases of a two-piece appliance, the rib has a flexible deflectable seal strip extending inwardly from its radially inner wall surface.
3. A member according to claim 1 or 2 in which the mouldable putty-like mass has very little or no memory, and is of a structure and consistency such that it can be spread with single digit motion and thereby spread out so that the space between the stoma and the radially inner edge of wafer is filled with the mouldable mass which is pressed to snugly surround the stoma.
4. A member according to claim 1 in which the mouldable mass is pressed and packed by the wearer into the space between the stoma and the body-side ring to form a doughnut-like cushioning and protective mass which is a snug, tailored fit within that space.

5. A member according to claim 1, 2 or 3 in which the mouldable putty-like mass is hydrocolloid-based.
6. A member according to claim 1, 2 or 3 in which the mouldable putty-like mass is hydrogel-based.
- 5 7. A member according to claim 1, 2 or 3 in which the mouldable putty-like mass is an adhesive which is plastic in nature during deformation by a digit, but after said deformation absorbs water and is thereby rendered elastic by cross-linking, so as to be no longer motile.
- 10 8. A body-side ostomy member in which an encircling rib thereof surrounds and confines a mouldable mass of non-hypoallergenic, substantially non-memory putty-like adhesive which is such that it can be finger-spread so that it forms a doughnut-like cushioning and protective mass surrounding the stoma.
- 15 9. A body-side ostomy member substantially as herein described with reference to and as illustrated in the accompanying drawings.
10. All novel aspects of the invention.

<p style="text-align: center;"><u>8</u></p> <p>Patents Act 1977 Examiner's report to the Comptroller under Section 17 (The Search report)</p>		<p>Application number GB 9515798.8</p>
<p>Relevant Technical Fields</p> <p>(i) UK Cl (Ed.N) A5R (RCED, RCG)</p> <p>(ii) Int Cl (Ed.6) A61F 5/443, 5/445, 5/448; A61L 15/00, 15/58</p> <p>Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications.</p> <p>(ii) ONLINE: WPI</p>		<p>Search Examiner L V THOMAS</p> <p>Date of completion of Search 31 OCTOBER 1995</p> <p>Documents considered relevant following a search in respect of Claims :- 1-9</p>

Categories of documents

X:	Document indicating lack of novelty or of inventive step.	P:	Document published on or after the declared priority date but before the filing date of the present application.
Y:	Document indicating lack of inventive step if combined with one or more other documents of the same category.	E:	Patent document published on or after, but with priority date earlier than, the filing date of the present application.
A:	Document indicating technological background and/or state of the art.	&:	Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
A	GB 2199250 A	(HOLLISTER) see page 7 line 15 to page 8 line 2	1, 8
A	GB 2157567 A	(CRAIG MEDICAL) see page 1 lines 18-49	1, 8
X	US 4204540	(CILENTO ET AL) see column 2 lines 14-42	8

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